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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,247	09/28/2004	Shunichi Kuroda	12480-000068/US	4500

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EXAMINER	
PENG, BO	
ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
05/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/509,247	KURODA ET AL.	
	Examiner	Art Unit	
	Bo Peng	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,5,7 and 17-20* is/are pending in the application.

4a) Of the above claim(s) *4,5,7,17 and 18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,19 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is in response to the amendment filed March 8, 2007. Claims 2, 3, 6 and 8-16 are cancelled. Claims 19 and 20 are newly added; Claims 1, 4, 5, 7 and 17-20 are pending. Claims 4, 5, 7, 17 and 18 were withdrawn as non-elected. Claims 1, 19 and 20 are considered in this office action.

Specification

2. The amended specification filed on March 8, 2007, is not accepted by the examiner because the use of trademarks has been noted in this amendment, e.g. QuickChange™ (see amendment, p. 3). Each letter of the trademarks should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The rejection of Claim 1 under 35 U.S.C. 112, first paragraph, for failing to comply with the enablement requirement **is maintained**, and is now extended to Claims 19 and 20.

5. Applicant argues that the specification is enabling because a pharmaceutical compound is described in the specification. The specification describes that the pharmaceutical compound contains a hepatitis virus surface-antigen protein capable of recognizing a hepatocyte and contains any one of an interferon, hepatocyte growth factor, or interleukin as a target cell substance. Furthermore, hepatitis B virus surface-antigen protein is capable of recognizing hepatocytes and has strong infectivity specific to hepatocytes. That is, the protein is capable of recognizing and binding with hepatocytes, and delivering the target-cell substance in particles into the hepatocytes. Therefore, the pharmaceutical compound transfers drugs efficiently to hepatocytes (target site). The compound may be administered in a relatively small amount and still be effective in liver disease treatment.

6. Applicant's argument is considered, but not persuasive because even though a carrier protein such as HBsAg can transfer drugs to hepatocytes, this does not necessarily make it a medicine. In order to provide proof of utility with regard to drugs and their uses, either clinical, *in vivo* or *in vitro* data, or a combination of these can be used. However, the data must be such as to convince one of ordinary skill in the art that the proposed utility is sufficiently established. See in re Irons, 340 F. 2d 924,144 USPQ 351 (CCPA 1965), Ex parte Krepelka, 231 USPQ 746 (PTO Bd. Pat. App & Inter.1986) and Ex pane Chwang. 231 USPQ 751 (PTO Bd. Pat. App & Inter. 1986). In the instant case, while the specification shows that HBsAg can deliver a report gene GFP to the hepatocyte, the specification does not show how the claimed pharmaceutical compounds, HBsAg/interferons (HBsAg/IFN), results in clinical benefit for treating viral hepatitis. The specification does not teach whether or not the IFN fused with HBsAg is biologically active, nor whether or not HBsAg/IFN can achieve an effective dose needed for

treating a viral infection since a certain dose of IFN is required for treating hepatitis. Without such teaching from the specification, one would not know whether or not the fused HBsAg/IFN could be used as a pharmaceutical compound for treating a disease. A rationale to use a HBsAg/IFN as a medicine for treating viral hepatitis, without presenting specific scientific data in the specification, is insufficient to convince one of ordinary skill in the art that the claimed pharmaceutical composition is effective for its intended use.

7. Since the HBsAg/IFN is not a conventional medicine known to one of ordinary skill in the art, one of ordinary skill in the art is unable to fully predict the possible properties/functions of the pharmaceuticals composition, therefore, clearly would not know how to use the claimed pharmaceutical composition. For the reason discussed above, the rejection of Claims 1, 19 and 20 for failing to comply with the enablement requirement is maintained.

35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. The rejection of Claim 1 under 35 U.S.C. 102(b), as being anticipated by Valenzuela, is withdrawn, in view of the amendment to the claim.

10. The rejection of Claim 1 under 35 U.S.C. 102(b), as being anticipated by Kingsman, is withdrawn, in view of the amendment to the claim.

Double Patenting

11. The rejection of Claim 1 under the nonstatutory double patenting over Claims 28 and 30-33 of co-pending application 10/220,125 **is maintained**. Applicant acknowledges the rejection and does not wish to prematurely respond.

12. The rejection of Claim 1 under the nonstatutory double patenting over Claims 1-7 and 9 of co-pending application 10/529,749 **is maintained**. Applicant acknowledges the rejection and does not wish to prematurely respond.

13. The rejection of Claim 1 under the nonstatutory double patenting over Claims 1 and 2 of co-pending application 10/509,248 **is maintained**. Applicant acknowledges the rejection and does not wish to prematurely respond.

Remarks

14. No claim is allowed. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The examiner can normally be reached on M-F, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, Ph. D. can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

BP
Bo Peng, Ph.D.
May 21, 2007

Bruce Campell

BRUCE R. CAMPELL, PH.D
SUPERVISORY PATENT EXAMINER
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